

REMARKS

The claims have been amended to place this application in condition for allowance. Specifically, claim 1 has been amended to include the limitation previously recited in claim 23 that the solid preparation recited in the claim does not contain sodium bicarbonate. Claim 23 has been cancelled. Claim 1 has also been amended to recite that in the second composition, the core particles are covered with a coating layer "consisting of said sugar or a different sugar." Finally, claim 1 has also been amended to recite the solid preparation as comprising granules of the first composition and granules of the second composition, the granules of the first composition and the granules of the second composition having about the same average particle diameter.

Claims 8 and 9 have also been amended to recite that in the process of preparing the solid preparation for dialysis of the present invention, the second coated particles are dried to obtain granules of the second composition having an average particle diameter of 300 to 1,700 μm and which is about the same average particle diameter as the granules of the first composition.

These amendments are believed to place the application in condition for allowance in view of telephone discussions between applicants' undersigned representative and the Examiner, Ms.

Gollamudi, in September, 2004. During the telephone discussions, the rejections in the Action were discussed. First, regarding the rejection of claims 1, 4, 7-9, 11 and 13-23 under 35 U.S.C. §112, second paragraph, as being indefinite, the undersigned explained that the preparation of the invention is a mixture of separate compositions, i.e., separately prepared granules of composition (1) and separately prepared granules of composition (2), and an acid. The undersigned noted that, to form a dialysate, the solid preparation of the invention is mixed with a solid preparation containing sodium bicarbonate and then the resultant mixture is dissolved in water.

Ms. Gollamudi indicated that, if we included such an explanation in the response, she will likely remove the § 112 rejection. However, to ensure that the claims are clear, claim 1 has been amended as noted above to precisely recite that the solid preparation for dialysis of the present invention comprises granules of a first composition and granules of a second composition and an acid.

Regarding the 35 U.S.C. § 102 and 35 U.S.C. § 103(a) rejections, the undersigned asked Ms. Gollamudi to explain her position regarding claim 23, which positively recites that the solid preparation does not contain sodium bicarbonate. The

undersigned noted that the Office Action does not separately explain the relevance of the prior art to claim 23. During our discussions, Ms. Gollamudi indicated that, in view of the explanation of the solid preparation of the present invention, claim 23 "appeared" to patentably distinguish over the cited references.

However, Ms. Gollamudi also recommended (as she has in the Action) amending the claims to recite, if supported in the specification, that the first and second compositions have the same particle size so as to provide for a homogeneous mixture. The undersigned explained to Ms. Gollamudi that the support in the specification for such an amendment is the description in the paragraph bridging pages 12 and 13, which describes that the first and second compositions are granulated into granules having an average particle diameter of 300 to 1,700 μm and that, by such process, the compositions can be mixed homogeneously, and Example 1, in which the compositions are granulated into granules having the same particle size. Ms. Gollamudi advised the undersigned that she had discussed these descriptions with her supervisor and they agreed that the descriptions would support the amendment concerning particle size. As noted above, the claims have now been amended to recite that the granules of the first composition and the granules

of the second composition have about the same average particle diameter.

In view of the amendments to the claims, it is respectfully submitted that the claims avoid the 35 U.S.C. § 112, 35 U.S.C. § 102 and 35 U.S.C. § 103(a) rejections and that these rejections should be removed.

Claims 1, 4, 7-9, 11 and 13-22 also stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent Nos. 6,407,070 and 6,489,301. Applicants respectfully request reconsideration of the double patenting grounds of rejection. The solid preparation for dialysis recited in the claims of the present application would not have been obvious to a person of ordinary skill in the art based on the compositions recited in the claims of the related patents. The forms of the compositions of the patents are entirely different from the preparation claimed in the present application. No motivation is provided for a person of ordinary skill in the art to modify the compositions of the patents to obtain the preparation of the present invention.

U.S. Patent No. 6,489,301 describes one solid concentrate for preparing a dialysis solution that includes sodium bicarbonate. The solid preparation of the present invention comprises three

separate components and excludes sodium bicarbonate. A composition consisting of one solid concentrate and containing sodium bicarbonate does not render obvious a composition of three specific separate components and not containing sodium bicarbonate. No art has been cited which provides a motive to modify the composition of the '301 patent as required to obtain the composition recited in the claims of the present application.

U.S. Patent No. 6,464,977 describes a solid preparation for dialysis in which the coating of the second composition comprises one or more electrolytes selected from the group consisting of sodium chloride, calcium chloride, magnesium chloride, potassium chloride and sodium acetate. The coatings of the second composition of the '977 patent are now positively excluded from the scope of the present claims by the recitation in the present claims of "consisting of." Additionally, nothing has been cited to support the obviousness of substituting a sugar as the coating of the second composition in the preparation of the '977 patent and providing granules of a second composition having an average particle diameter that is about the same as the average particle diameter as the granules of the first composition.

Removal of the double patenting grounds of rejection is in order and is respectfully solicited.

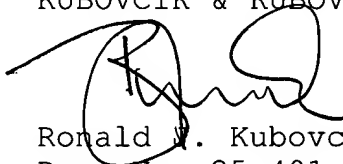
The foregoing is believed to be a complete and proper response to the Office Action dated July 21, 2004, and is believed to place this application in condition for allowance. If, however, minor issues remain that can be resolved by means of a telephone interview, the Examiner is respectfully requested to contact the undersigned attorney at the telephone number indicated below.

In the event that this paper is not considered to be timely filed, applicant(s) hereby petition(s) for an appropriate extension of time. The fee for any such extension may be charged to our Deposit Account No. 111833.

In the event any additional fees are required, please also charge our Deposit Account No. 111833.

Respectfully submitted,

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